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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,557	01/03/2002	Terry M. Fredeking	7841P001	8399

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EXAMINER
CHONG, YONG SOO

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
11/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/038,557	FREDEKING ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16,18-22 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16, 18-22, 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 8/28/2007. Claim(s) 1-12, 17, 23 have been cancelled. Claim(s) 13-16, 18-22, 24-26 are pending. Claim(s) 13 and 21 have been amended. Claim(s) 13-16, 18-22, 24-26 are examined herein.

Applicant's amendments have rendered all of the rejections of the last Office Action moot, therefore hereby withdrawn. The following new rejection will now apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-16, 18-22, 24-26 are rejected under 35 U.S.C. 103(a) as being obvious over Jacobson et al. (*N. Engl. J. Med.* 1997 May 22, 336 (21): 1487-93) in view of Golub et al. (US Patent 6,015,804).

The instant claims are directed to a process comprising contacting blood or a fraction thereof with a tetracycline both *in vivo* and *in vitro* and then isolating the blood or fraction thereof.

Jacobson et al. discloses treatment of oral ulcers in HIV patients by administrating thalidomide (abstract). Laboratory assays from the blood of the patients were taken to measure for cytokines and cytokine receptors. Measurements of plasma samples resulted in increased levels of tumor necrosis factor and tumor necrosis factor receptors (pg. 1488, right column, second paragraph). Jacobson et al. also teach that thalidomide is well known to inhibit production of tumor necrosis factor (pg. 1487, right column, third paragraph).

Examiner notes that taking laboratory assays from the blood of the patients inherently meets the limitation regarding isolating the blood or the fraction thereof. Furthermore, Jacobson et al. discloses measuring the plasma samples, which inherently meet the limitation regarding further processing of the isolated blood by means such as centrifugation. Upon centrifugation, blood is inherently separated into fractions containing globulin, anti-hemophilia factor, albumin, serum, and plasma.

Examiner also notes that the limitation regarding a three-fold increase of cytokine receptors as a result of administration of a tetracycline is inherent since a composition and its properties are inseparable. "Products of identical chemical composition can not

have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Furthermore, the list of diseases are considered preamble and also will not be given any patentable weight. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

Jacobson et al. teach as discussed above, however fail to specifically disclose contacting the blood with tetracycline *in vitro*.

Golub et al. teach a method of treating medical conditions characterized by excessive TNF-alpha production (abstract). Such diseases or conditions include viral infections, inflammation, diabetes, cancer, graft versus host disease, inflammatory bowel disease, arthritis, autoimmune disorders, and rheumatoid arthritis (col. 2, lines 6-18). (col. 2, lines 6-18). Golub et al. teach that such methods is useful in enhancing IL-10 production, which is known to inhibit or down regulate IL-1 and TNF-alpha production (col. 5, lines 43-45). Therefore, Golub et al. teach a method of contacting tetracycline with blood *in vitro* in order to measure increases in levels of cytokines, such as IL-10 (col. 5, lines 54-55; col. 8, lines 8-12; and examples), which then can be administered to treat the above diseases or conditions.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, for Jacobson et al. to have also performed the *in vitro* procedure of contacting the blood or a fraction thereof with a tetracycline as disclosed by Golub et al.

A person of ordinary skill in the art would have been motivated to perform the *in vitro* procedure of contacting the blood or a fraction thereof with a tetracycline or because: (1) both Jacobson and Golub et al. disclose methods of treating patients with viral infections; (2) both Jacobson and Golub et al. teach a need to inhibit production of TNF-alpha since excessive TNF-alpha production leads to various diseases; (3) Jacobson et al. teaches that thalidomide is well known to inhibit production of TNF-

alpha; and (4) Golub et al. also teach the functional equivalence of tetracycline since it is also well known to inhibit production of TNF-alpha. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in inhibiting TNF-alpha as disclosed by Jacobson et al. with tetracycline as disclosed by Golub et al. via the process of contacting the blood or a fraction thereof and subsequently isolation.

Response to Arguments

Applicant continues to argue that the cited prior art does not teach "administrating the blood or fraction thereof to treat a disease, condition, or disorder." Again, Applicant is reminded that the claims are drawn to a process of contacting the blood with a tetracycline and not to treat a disease. The limitations involving treating a disease or condition are considered an intended use and will not be afforded much patentable weight.

Applicant argues that the claims are drawn to a process and not a product, therefore *In re Spada* case law is not applicable. Again, Applicant is reminded that the process claims involve a composition, which inherently possess the same properties as the instantly claimed composition. Applicant does not argue that the components or the dosage is different, therefore how could the properties differ as well. Applicant is encouraged to show a side-by-side comparison of how one composition possesses the claimed properties and how the other does not.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER